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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/997,601 | 11/15/2001 | Avi J. Ashkenazi | P2730PIC36 | 5112 |

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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,601

Applicant(s)

ASHKENAZI ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119, 120 and 122-124 is/are rejected.
- 7) ☒ Claim(s) 121 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0304, 0703, 1007, 0502.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The preliminary amendments filed 09/03/2002 and 11/15/2001 have been entered.

Claims 119-124 are pending and being examined.

5

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

10

Priority

According to the communication of 09/03/2002, the present application is claiming priority under 35 U.S.C. 120 and 119 (e) to earlier filed applications. Under 35 U.S.C. 120, the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by 35 U.S.C. 112, first paragraph in the earlier filed application. Under 35 U.S.C. 119 (a) or (e), the claims in a U.S. application are entitled to the benefit of a foreign priority date or the filing date of a provisional application if the corresponding foreign application or provisional application supports the claims in the manner required by 35 U.S.C. 112, first paragraph. A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph.

20

The earliest filed prior application that establishes a utility for the presently claimed antibodies that bind the PRO1186 polypeptide (SEQ ID NO: 371) and, hence, provides a disclosure in the manner provided by 35 U.S.C. 112, first paragraph, is U.S.

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Application No. 60/145,698 (filed 07/26/1999), which discloses the ability of the PRO1186 polypeptide to stimulate adrenal cortical capillary endothelial cell (ACE) growth. Accordingly, the effective filing date of the presently claimed compounds is 07/26/1999.

5 Should Applicants disagree with the examiner's determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 07/26/1999 which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to
10 07/26/1999.

 According the preliminary amendment filed 09/03/2002 this application is a CON of 09/941,992, filed 08/28/2001, which claims the benefit of 60/213,637, filed 06/23/2000, and 60/230,978, filed 09/07/2000. The benefit claim to 60/213,637, filed
15 06/23/2000, is not proper because it must be filed within twelve months from the filing date of the provisional application. Any nonprovisional application that directly claims the benefit of a provisional application under 35 U.S.C. § 119(e) must be filed within twelve months from the filing date of the provisional application. If a benefit claim to a provisional application is submitted without an indication that an intermediate
20 nonprovisional application directly claims the benefit of the provisional application and the instant nonprovisional application is not filed within the twelve month period, the Office will not have sufficient information to enter the benefit claim into the computer database. Therefore, the Office will not recognize such a benefit claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

5 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 124 is indefinite over the recitation of “specifically binds.” Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of “specifically binds” an artisan cannot
10 determine what additional or material functional limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that
15 form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

20 Claims 119, 120, 123, 124 are rejected under 35 U.S.C. 102(a) as being anticipated by MILNE EDWARDS JEAN-BAPTISTE (WO 99/06550, cited by Applicants).

This rejection is based upon an effective filing date of 07/26/1999 for the presently claimed invention.

25 MILNE EDWARDS JEAN-BAPTISTE discloses a 5' EST encoding a polypeptide that is almost identical to a portion of the present application's SEQ ID NO: 371, as indicated below (Db = MILNE EDWARDS JEAN-BAPTISTE's polypeptide):

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Query Match 76.7%; Score 452; DB 2; Length 81;
 Best Local Similarity 98.8%; Pred. No. 5.1e-40;
 Matches 80; Conservative 1; Mismatches 0; Indels 0; Gaps 0;

5 Qy 1 MRGATRVSIMLLLVTVSDCAVITGACERDVQCGAGTCCAISLWLRGLRMCTPLGREGEEC 60
 |||||
 Db 1 MRGATRVSIMLLLVTVSDCAVITGACERDVQCGAGTCCAISLWLRGLRMCTPLGREGEEC 60
 10 Qy 61 HPGSHKVPFFRKRKHHTCPCL 81
 |||||:|||||
 Db 61 HPGSHKIPFFRKRKHHTCPCL 81.

MILNE EDWARDS JEAN-BAPTISTE also discloses labeled and unlabelled

monoclonal and polyclonal antibodies that bind the polypeptide (page 7, full paragraph 2;

page 61, full paragraph 1; paragraph bridging pages 62-63; pages 84-86; page 92). Such

15 antibodies would also bind the polypeptide shown in Figure 266 (SEQ ID NO: 371) in

the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

20 obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.
 25 Patentability shall not be negated by the manner in which the invention was made.

Claims 119, 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over

MILNE EDWARDS JEAN-BAPTISTE (WO 99/06550, cited by Applicants) as applied

to claim 199 above and further in view of Brandon (U).

30 MILNE EDWARDS JEAN-BAPTISTE teaches antibodies that bind the

polypeptide shown in Figure 266 (SEQ ID NO: 371), as discussed above. MILNE

EDWARDS JEAN-BAPTISTE does not teach antibody fragments that bind the

polypeptide shown in Figure 266 (SEQ ID NO: 371).

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Brandon teaches improved immunocytochemical staining through the use of Fab fragments of primary antibody (Abstract). Brandon does not teach antibody fragments that bind the polypeptide shown in Figure 266 (SEQ ID NO: 371).

However, it would have been obvious to one of ordinary skill in the art at the time of

5 Applicants' invention to make antibodies that bind the polypeptide shown in Figure 266 (SEQ ID NO: 371), as taught by MILNE EDWARDS JEAN-BAPTISTE, and to modify that teaching by making Fab fragments, as taught by Brandon, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because immunocytochemical staining can be improved through the use of
10 Fab fragments. The invention is prima facie obvious over the prior art.

Conclusion

Claim 121 is objected to as being dependent upon a rejected base claim.

15 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571)272-0961.

20 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHT FAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

25 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

30 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

35 DSR
AUGUST 3, 2004